REMARKS

Claims 28, 29, 31, 36-38 and 40, 41, and 46-56 are pending in the application, of which claims 38 and 40-56 are currently under consideration. Claims 39 and 42-45 have been canceled without prejudice or disclaimer. Applicants expressly reserve the right to pursue the subject matter of those claims in one or more subsequent applications. Claims 38, 40, 41, and 46-56 have been amended. Claim 38 has been amended to delete certain non-elected subject matter. Applicants expressly reserve the right to pursue the deleted subject matter in one or more subsequent applications. Claims 40, 41, and 46-56 have been amended to even more clearly recite the claimed invention.

Finality of Office Action

In a voicemail message left with the undersigned on May 24, 2004, Examiner Brannock stated that the present Office Action is not a Final Office Action and that he had mistakenly checked Box 2a, which states that "[t]his action is FINAL." *See* Office Action Summary. The undersigned called the Office of Initial Patent Examination and they confirmed that the PALM system indicates that the present Office Action is non-final. Accordingly, applicants address the present Office Action as a non-final Office Action.

Maintained Objection and Rejections

Objection

The Examiner objected to claims 38-41 and 46 for allegedly encompassing "several non-elected patentably distinct inventions." Action at page 2. The Examiner stated that "[a]pplicant is required to delete the non-elected inventions of 38(b) and 38(c)." *Id.*

Solely to expedite prosecution and without acquiescing to the objection, applicants have deleted the subject matter of subparts (b) and (c) of claim 38 and have canceled claim 39 without prejudice or disclaimer. Each of claims 40, 41, and 46 depends from claim 38. Applicants reserve the right to pursue the deleted subject matter in one or more subsequent applications.

Applicants assert that the amendment to claim 38 obviates the Examiner's objection. Applicants respectfully request reconsideration and withdrawal of the objection to claims 38, 40, 41, and 46. As that objection was the only remaining objection or rejection of claims 38, 40, 41, and 46, applicants respectfully assert that those claims are now allowable.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 42-45 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pasquale EB (1991) *Cell Regulation*, 2: 523-534 (Pasquale) in view of U.S. Patent No. 4816567 (the '567 patent). Action at page 3.

Solely to expedite prosecution and without acquiescing to the rejection, applicants have canceled claims 42-45. Applicants respectfully assert that the rejection under 35 U.S.C. § 103(a) over Pasquale in view of the '567 patent is rendered moot by the cancellation of those claims.

The Examiner rejected claims 42-45 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Iwase et al. (1993) *Biochem. Biophys. Res Comm.*, 194(2): 698-705 (Iwase) in view of the '567 patent, for the reasons set forth in item no. 10 of Paper No. 19. Action at page 4.

Solely to expedite prosecution and without acquiescing to the rejection, applicants have canceled claims 42-45. Applicants respectfully assert that the rejection under 35 U.S.C. § 103(a) over Iwase in view of the '567 patent is rendered moot by the cancellation of those claims.

New Rejections

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 40 and 41 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Action at page 6. Specifically, the Examiner alleged that "[c]laims 40 and 41 are worded in a such a way as to require that the fragment be a chimeric antibody. A fragment of an antibody cannot be, itself, a chimeric antibody or a CDR-grafted antibody." Action at page 7.

Solely to expedite prosecution and without acquiescing to the rejection, applicants have amended claims 40, 49, and 54 to recite "The antibody or fragment thereof . . . which is a chimeric antibody or a chimeric antibody fragment." Solely to expedite prosecution and without acquiescing to the rejection, applicants have amended claims 41, 50, and 55 to recite "The antibody or fragment thereof . . . which is a CDR-grafted antibody or a CDR-grafted antibody fragment."

Applicants assert that an antibody fragment can be chimeric or CDR-grafted. As a non-limiting example, an antibody fragment having a mouse variable region and a portion of a human constant region, i.e., a mouse/human chimeric antibody fragment, is still chimeric even though it is an antibody fragment. As a further non-limiting example, a CDR-grafted antibody fragment that has a CDR-grafted variable region and only a portion of the constant region is still CDR-grafted even though it is an antibody fragment. Thus, applicants assert that claims 40 and 41 (and also claims 49, 50, 54, and 55) are definite.

Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 47-56 under 35 U.S.C. § 112, first paragraph, alleging that the specification "does not reasonably provide enablement for fragments that are raised against a polypeptide of SEQ ID NO: 11 or that do not bind a polypeptide of SEQ ID NO: 11." Action at page 7. Specifically, the Examiner alleged that "the claims require that the fragment be raised against the polypeptide, which is impossible." The Examiner further alleged that "there is no limitation that requires that the fragment be that part of the antibody that binds to the polypeptide." *Id.*

Applicants respectfully traverse. Solely to expedite prosecution and without acquiescing to the rejection, applicants have amended claim 47 to recite "[a]n antibody or fragment thereof which is raised against a polypeptide comprising SEQ ID NO: 11, wherein the antibody or fragment thereof binds the polypeptide comprising SEQ ID NO:

11." Claims 48-51 depend from claim 47. Solely to expedite prosecution and without acquiescing to the rejection, applicants have amended claim 52 to recite "[a]n antibody or fragment thereof which is raised against a polypeptide comprising amino acids 1 to 524 of SEQ ID NO: 11, wherein the antibody or fragment thereof binds the polypeptide comprising amino acids 1 to 524 of SEQ ID NO: 11." Claims 53-56 depend from claim 52.

First, applicants assert that, contrary to the Examiner's contention, one skilled in the art can raise an antibody fragment to a particular antigen, e.g., by using phage display technology. Phage display of antibody fragments and its use in selecting specific antibodies was known in the art by the earliest priority date of the present application, e.g., by April 15, 1994. Applicants enclose a copy of an abstract for a review article entitled "Production of human antibodies using bacteriophage," which was published in 1993. That abstract discusses production of "human antibody fragments of high affinity and specificity . . . without immunization" using phage display technology. Griffiths AD (1993) *Curr. Opin. Immunol.*, 5: 263-267, at Abstract (emphasis added). Thus, applicants assert that it was not only possible, but known in the art at the time of filing, to raise an antibody fragment against a specific antigen. Therefore, claims 47 and 52 are fully enabled. Claims 48-51 depend from claim 47 and claims 53-56 depend from claim 52, so those claims are also enabled for at least the reasons discussed above for claims 47 and 52.

Second, solely to expedite prosecution and without acquiescing to the rejection, applicants have amended claims 47 and 52 to even more clearly indicate that the recited fragments are capable of binding to the antigen against which they were raised.

Claims 48-51 depend from claim 47 and claims 53-56 depend from claim 52, so those claims also recite fragments that are capable of binding to the antigen against which they were raised.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 47-56 under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claims 47-56 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kirby, J. (1992) *Immunology*, W.H. Freeman and Company, pages 100-101 (Kirby). Action at page 8. Specifically, the Examiner alleged that "claims 47 and 52 do not place any limitations on the claimed antibody fragment, thus the claims encompass the constant region of the antibody (Fc). A fragment consisting of the Fc portion is taught by Kirby." *Id.*

As discussed above, solely to expedite prosecution and without acquiescing to the rejection, claim 47 has been amended to recite "wherein the antibody or fragment thereof binds the polypeptide comprising SEQ ID NO: 11," and claim 52 has been amended to recite "wherein the antibody or fragment thereof binds the polypeptide comprising amino acids 1 to 524 of SEQ ID NO: 11."[1] Claims 48-51 depend from claim 47 and claims 53-56 depend from claim 52.

Applicants assert that those amendments obviate the rejection under 35 U.S.C. § 102(b) because Kirby does not teach or suggest an antibody or fragment thereof that

[1] Of course, those amendments do not preclude the possibility that the claimed antibodies cross-react with other polypeptides.

"binds the polypeptide comprising SEQ ID NO: 11" or an antibody or fragment thereof that "binds the polypeptide comprising amino acids 1 to 524 of SEQ ID NO: 11."

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 47-56 under 35 U.S.C. § 102(b) over Kirby.

Applicants respectfully assert that the present application is in condition for allowance and request that the Examiner issue a timely Notice of Allowance. If the Examiner does not consider the application to be allowable, the undersigned requests that, prior to taking action, the Examiner call her at (650) 849-6656 to set up at interview.

Please grant any extensions of time required to enter this Amendment and Response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 1, 2004

By: _____

Rebecca B. Scarr
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1: Curr Opin Immunol. 1993 Apr;5(2):263-7. Related Articles, Linl

Production of human antibodies using bacteriophage.

Griffiths AD.

MRC Centre for Protein Engineering, MRC Centre, Cambridge, UK.

The immune system produces antibodies by a process of antigen-driven selection. An in vitro process of antigen-driven selection, based on the displa of antibody fragments on filamentous bacteriophage, has recently been developed. This enables human antibody fragments of high affinity and specificity to be produced without immunization.

Publication Types:
- Review
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